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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,099	11/21/2001	Scott A. Lesley	P0012US20	1291

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/990,099	Applicant(s) LESLEY ET AL.	
	Examiner Daniel M Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to the "Response to Restriction Requirement" filed October 22, 2002 (Paper No. 12) in reply to the restriction requirement mailed May 21, 2002 (Paper No. 9). Claims 1-76 are pending in the application.

Response to inquiry as to status of Preliminary Amendment and Request for Correction of Filing Receipt

The PTO file does not contain the Preliminary Amendment or Request for Correction of Filing Receipt referred to in Paper No. 12.

Election/Restrictions

The following new restriction requirement is necessitated by the inadvertent omission of claims 56-76 in Paper No. 9.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, drawn to a host cell that comprises a solubility reporter nucleic acid and a target polypeptide-expressing nucleic acid, classified in class 435, subclass 325.

II. Claims 34-36, drawn to an array of two or more populations of host cells of Group I, classified in class 435, subclass 6.

III. Claims 37-62, drawn to a method of identifying mutations in a cell that alter the solubility of a target polypeptide, classified in class 435, subclass 6.

IV. Claims 37-55 and 63, drawn to a method for identifying alterations to a polynucleotide that encodes a target polypeptide that alter the solubility of the target polypeptide, classified in class 435, subclass 6.

V. Claims 37-55 and 64-66, drawn to a method to identify variations in a process for biosynthesis of a target polypeptide that alter the solubility of the target polypeptide, classified in class 435, subclass 6.

VI. Claims 37-55 and 67-70, drawn to a method of screening an expression library to identify library members that express a soluble target polypeptide, classified in class 435, subclass 6.

VII. Claims 37-55, 71 and 72, drawn to a method of identifying an antibiotic agent, classified in class 435, subclass 6.

VIII. Claims 73-76, drawn to a method of identifying a promoter that is differentially regulated in response to expression of an insoluble polypeptide in a host cell that comprises the promoter, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination as claimed is not solely dependent upon the particulars of the subcombination as claimed because patentability of an array is derived from the aggregate of

different host cells comprised by the array and not any single host cell within the array. The subcombination has separate utility as illustrated by its use in each of the methods of Groups III-VII.

Groups III-VII are distinct, each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to a method of using the host cell of Group I or the array of Group II. The Inventions are not disclosed as capable of use together in a single process and have different modes of operation, which are dictated by their different functions. For example: the method of Group III comprises the step of treating a cell with a mutagen, which is not comprised by the methods of Groups IV-VII; the method of Group IV comprises the step of altering a polynucleotide that encodes the target polypeptide to form an altered polynucleotide, which is not comprised by the methods of Groups III and V-VII; the method of Group V comprises the step of culturing a host cell under alternative conditions in which the target polypeptide is expresses, which is not comprised by the methods of Groups III, IV, VI and VII; the method of Group VI comprises the step of introducing a plurality of expression vectors that each comprise a polynucleotide that encodes a target polypeptide into a plurality of host cells to create an expression library, which is not comprised by the methods of Groups III-V and VII; and the method of Group VII comprises the step of contacting a cell that comprises a solubility reporter agent with a candidate antibiotic agent, which is not comprised by the methods of Groups III-VI.

The method of Group VIII is distinct from each of the products of Groups I and II and each of the methods of Groups III-VII in being directed to a method of using a cell comprising a

target polypeptide that can be expressed in insoluble form for the purpose of identifying a promoter that is differentially regulated in response to expression of an insoluble polypeptide. As the products of Groups I and II are specifically directed to host cells comprising solubility reporter nucleic acids, they could not be used in the method of Group VIII because the presence of known solubility reporter nucleic acids would interfere with the attempts to identify other nucleic acids having that same activity.

Groups I and II are related to the methods of Groups III-VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups I and II can be used in each of the distinct processes of Groups III-VII.

Each of Groups I and III-VII identified above is further restricted to a host cell comprising, or method of using a host cell comprising, single distinct nucleic acid sequence selected from the group consisting of SEQ ID NO:1-43 and polynucleotide that comprise a regulatory region of a gene listed in Table 1 (claim 4). Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because they are structurally distinct and there is no disclosed correlation between the structure of the nucleic acid sequences to which the claims are directed and their function in a solubility reporter.

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Claims 1 and 37 link(s) the inventions of Groups I and III-VII, respectively, as they are directed to host cells comprising and methods of using host cells comprising distinct nucleic acid sequences. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 or 37. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Response to Arguments

In response to the restriction requirement set forth in Paper No. 9, Applicant traverses on the grounds that the restriction is improper because the application contains claims that are generic to all the claimed species. Applicant cites 37 C.F.R. § 1.141, which states "more than

one species of invention...may be specifically claimed in different claims in one national application, provided that the application also includes an *allowable* claim generic to all the claimed species..." (emphasis added). As stated in the original restriction requirement, "[t]he restriction requirement between the linked inventions is subject to the *nonallowance* of the linking claim(s)..." (page 2, paragraph 2; emphasis added). It therefore appears that Applicant has misunderstood the conditions of the restriction requirement as set forth in Paper No. 9 and again herein above as the claims are newly restricted. According to the present restriction requirement, claims 1 and 37 are generic to all Inventions within the groups that comprise them as they are distinguished based on the identity of the solubility responsive promoter. These claims are thus proper linking claims and, as described above, will be examined commensurate with their full scope. If there are no substantive grounds for rejection of the linking claims then all claims directed to individual embodiments of the invention, which are distinguished by the solubility responsive promoter, will be examined together.

Thus, Applicant's concern that the restriction requirement amounts to rejection of the generic claim (first stated in the second paragraph on page 7) is unfounded. In contrast, according to the conditions of the restriction requirement, patentability of the generic claim within the elected group will be considered first, and if the generic claim is found to be allowable the distinct embodiments comprised within the generic claim will then be considered in the instant application.

In the first paragraph on page 7, applicant identifies claims 56, 63, 64, 67, 71 and 74 as proper generic claims. However, none of the claims or their dependent claims are directed to a

method comprising a specifically named protein solubility responsive promoter. Therefore, linking claim practice is not in effect for these claims.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/990,099

Art Unit: 1636

dms
December 19, 2002

JAMES KETTER
PRIMARY EXAMINER